

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESALE PRICE	)	MDL NO. 1456
LITIGATION	)	Civil Action No. 01-12257-PBS
	)	Subcategory Case No: 03-10643-PBS
THIS DOCUMENT RELATES TO:	)	
	)	Judge Patti B. Saris
<i>The City of New York, et al.</i>	)	
	)	
v.	)	
	)	
<i>Abbott Laboratories, et al.</i>	)	
	)	

**PLAINTIFFS' LOCAL RULE 56.1  
STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO  
WATSON PHARMACEUTICALS, INC. AND WATSON PHARMA, INC.**

Pursuant to Rule 56.1 of the Local Rules of this Court, plaintiffs hereby submit their Statement of Undisputed Material Facts Applicable to Watson Pharmaceuticals, Inc. and Watson Pharma, Inc. (collectively "Watson") in support of their Motion for Partial Summary Judgment.

**I. WATSON SPECIFIC FACTS**

1. The Watson Drugs and NDCs that have been examined in connection with this motion are set forth in Exhibit A hereto. This exhibit also sets forth Watson's Published AWP's and WACs for these Drugs and NDCs, any operative Federal Upper Limits ("FUL") and Watson's AMPs. That exhibit notes which NDCs are associated with package sizes that set the FUL.

2. The specific Watson drugs at issue are the Albuterol 90 MCG Inhaler, Clonazepam .5 MG Tablet, Enalapril Maleate 20 MG Tablet, Lorazepam 1 MG Tablet, Metoprolol 100 MG Tablet and Ranitidine 150 MG Tablet.

### **Watson and Schein**

3. Watson Pharma, Inc. was formerly known as Schein and has been a wholly-owned subsidiary of Watson Pharmaceuticals, Inc. since 2000. Answer and Affirmative Defenses of Watson Pharmaceuticals, Inc. and Watson Pharma, Inc. to Revised First Amended Consolidated Complaint [Docket # 4858] (“Watson Answer”) ¶46<sup>1</sup>

### **Watson’s Knowledge of the Federal Medicaid Rebate Agreement**

4. Watson has entered into and executed the federal Medicaid rebate agreement pursuant to 42 U.S.C. § 1396r-8. *See* Watson Answer at ¶68; *Commonwealth of Mass. v. Mylan*, 2008 WL 5650859 (D.Mass) (“*Mylan*”) at \*22.

5. Watson was required as matter of law to familiarize itself with the legal requirements, standards and procedures of the Medicaid program. *Mylan*, 2008 WL 5650859 at \*25.

6. Watson is aware of State Medicaid reimbursement formulas. *See* Deposition of Lisa Recchia dated 10/11/07 (“Recchia 10/11/07 Dep.”) (Exhibit B) at 155:3-158:19; *see also* Exhibit C (Recchia 10//11/07 Dep. Exhibit 23 (email, dated 11/17/99, from Lisa Recchia with attached gross profit analysis demonstrating a reimbursement formula of AWP minus 13)).

7. Watson knew and understood that most drugs purchases are paid for by third-party payors, including Medicaid, and not by cash paying customers. *See* Exhibit D (Schein 30(b)(6) (Clark) Dep. Exhibit 4 (Schein memo dated February 17, 1998, stating that most pharmacists average from seventy to a hundred percent third-party prescriptions)).

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<sup>1</sup> Hereinafter, references to the practices or knowledge of Watson shall include Watson and Schein during the period 1997-2005 unless Schein’s practices or knowledge differed, in which case Schein will be separately identified.

8. Watson knew that third-party payors, including state Medicaid programs, used SWP, AWP and WAC to set reimbursement rates for drugs. *See* Watson Pharmaceuticals, Inc. 30(b)(6) (Andrew Boyer) dated 6/27/07 (“Watson 30(b)(6) (Boyer) 6/27/07 Dep.”) (Exhibit E) at 110:6-111:22; Schein 30(b)(6) (Napoleon Clark) dated 6/27/07 (“Schein 30(b)(6) (Clark) 6/27/07 Dep.”) (Exhibit F) at 47:20-48:61; *see also* Recchia 10/11/2007 Dep. (Exhibit B) at 28:13-33:21; Exhibit G (Recchia 10/11/07 Dep. Exhibit 1 (price verification form sent from FDB to Lisa Recchia at Schein, dated November 17, 1995, explaining that several states use wholesale prices as the basis for Medicaid reimbursement)).

#### **Watson Set and Reported Its AWP and WACs<sup>2</sup>**

9. For each of its generic drugs, Watson generally set the AWP at about 10% to 11% below the corresponding brand AWP. *See* Schein 30(b)(6) (Clark) 6/27/07 Dep. (Exhibit F) at 41:10-16 and 76:07-14; Deposition of Napoleon Clark dated 12/01/05 (“Clark 12/1/05 Dep.”) (Exhibit H) at 39:15-40:08; Watson Pharmaceuticals, Inc. 30(b)(6) (Andrew Boyer) dated 6/27/07 (“Watson 30(b)(6) (Boyer) 6/27/07 Dep.”) (Exhibit E) at 90:7-13. If there was other generic competition for the product, then Watson set AWP at or near the AWP set by the competing generic manufacturers selling the same generic drug. *See* Watson 30(b)(6) (Boyer) 6/27/07 Dep. (Exhibit E) at 91:12-92:16; Schein 30(b)(6) (Clark) 6/27/07 Dep. (Exhibit F) at 41:10-16 and 45:4-17; *see also* Recchia 10/11/07 Dep. (Exhibit B) at 118:14-120:3.

10. Watson set its WAC for new products at 20 to 25 percent off of AWP. *See* Clark 12/1/05 Dep. (Exhibit H) at 41:9-14; *see also* Watson 30(b)(6) (Boyer) 6/27/07 Dep. (Exhibit E)

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<sup>2</sup> Lisa Recchia testified that the policies of Watson and Schein for setting WACs and AWP were similar. *See* Recchia 10/11/07 Dep. (Exhibit B) at 122:1-7.

at 91:7-11. For products in competitive markets, Watson sets the WAC by comparing its price to that of its competitors' WACs. *See* Clark 12/1/05 Dep. (Exhibit H) at 41:9-42:2.

**11.** Before 2000, Watson reported only AWP to FDB. In 2000, Watson switched from reporting AWP to reporting a "Suggested Wholesale Price" or "SWP." *Mylan* at \*9. However, Watson knew that SWP represented the same price as AWP. *See* Watson 30(b)(6) (Boyer) 6/27/07 Dep. (Exhibit E) at 60:22-61:6.

**12.** In addition to AWP and SWP, Watson at times reported WAC or WHNET to FDB. *See* Watson 30(b)(6) (Boyer) 6/27/07 Dep. (Exhibit E) at 65:5-69:4; *see* Schein 30(b)(6) (Clark) 6/27/07 Dep. (Exhibit F) at 28:3-30:22; Exhibit I (Schein 30(b)(6) (Clark) 6/27/07 Dep. Exhibit 2 (Schein product status report, dated March 20, 1996)); *see also* Recchia 10/11/07 Dep. (Exhibit B) at 28:13-30:15, 39:05-12; Exhibit G (Recchia 10/11/07 Dep. Exhibit 1 (price verification form sent from FDB to Lisa Recchia at Schein, dated November 17, 1995, listing AWP and WHLNETs)); *see also* Schein 30(b)(6) (Napoleon Clark) dated 6/28/07 ("Schein 30(b)(6) (Clark) 6/28/07 Dep.") (Exhibit J) at 113:22-115:3; *see* Clark 12/01/05 Dep. (Exhibit H) at 137:18-140:14; Exhibit K (Clark 12/01/05 Dep. Exhibit 14 (Schein letter, dated May 27, 1998, communicating AWP, WAC and direct price changes)).

### **Watson's Knowledge of the Federal Upper Limits and Maximum Allowable Cost**

**13.** Watson knew that the Federal Upper Limit (FUL) limited the reimbursement paid by third-party payors. *See* Recchia 10/11/07 Dep. (Exhibit B) at 146:11-152:2; Exhibit L (Recchia 10/11/07 Dep. Exhibit 21 (Schein memo, dated 8/27/96, approving a strategy intended to increase FUL)).

### **Watson Paid Wholesalers Chargebacks and Rebates**

**14.** At all times from 1997 to 2005, Watson sold drugs to the three national wholesalers and/or one of their predecessor companies. *See* Watson Pharmaceuticals, Inc. 30(b)(6) (Andrew Boyer) dated 7/14/04 (“Watson 30(b)(6) (Boyer) 7/14/04 Dep.”) (Exhibit M) at 20:9-17; *see also* Exhibit N (Watson 30(b)(6) (Boyer) 7/14/04 Dep Exhibit 11 (Schein letter to McKesson, dated October 20, 1999, with attached Select Generics Program Supplier Agreement)); *see also* Exhibit O (Watson 30(b)(6) (Boyer) 7/14/04 Dep. Exhibit 12 (Schein document, Response to Terms and Conditions AmeriSource SELECT)).

**15.** Watson pays the wholesalers chargebacks and rebates that reduce the wholesalers net cost. *See* Recchia 10/11/07 Dep. (Exhibit B) at 197:16-200:22; Exhibit P (Recchia 10/11/07 Dep. Exhibit 10 (Schein memo from Lisa Recchia, dated December 6, 1996); *see also* Deposition of Kathleen Barclay dated 11/21/05 (“Barclay 11/21/05 Dep.”) (Exhibit Q) at 45:9-14. Watson knew that non-warehousing chains purchased Watson’s products from wholesalers below WAC, and the wholesalers received chargebacks from Schein, resulting in a net cost to the wholesaler of WAC less the chargeback. *See* Recchia 10/11/07 Dep. (Exhibit B) at 116:4-117:9; Exhibit R (Recchia 10/11/07 Dep. Exhibit 13 (Schein pricing grid)).

#### **Other Watson Customers Received Rebates**

**16.** Watson knew that customers such as Kerr Drug, Publix, and Winn Dixie, who purchase Watson drugs through wholesalers, received pass-through rebates from wholesalers in the form of credit. *See* Barclay 11/21/05 Dep. (Exhibit Q) at 45:19-46:16.

**17.** For the period between 1997 and 2005, Watson offered rebates of 2% to 19% off of net sales to various classes of trade. *See* Barclay 11/21/05 Dep. (Exhibit Q) at 104:5-111:20 and 113:7-114:8; Exhibit S (Barclay 11/21/05 Dep. Exhibit 4 (June 14, 1994 memo describing

rebates for warehousing and non-warehousing chains as high as 8 percent off net sales; and administrative fees for nursing homes, hospitals and GPOs of 2 percent)).

**Watson's Published AWP and WACs had No Relationship to Actual Prices**

**18.** Watson knows that none of its customers pay AWP for generic drugs (*see* Barclay 11/21/05 Dep. (Exhibit Q) at 96:9-10; *see also* Schein 30(b)(6) (Clark) 6/27/07 Dep. (Exhibit F) at 44:7-21; *see* Recchia 10/11/07 Dep. (Exhibit B) at 202:7-12).

**19.** With increasing competition, the price Watson charged its customers would decline as Watson's AWP and WACs normally increased. *See* Watson 30(b)(6) (Boyer) 6/27/07 Dep. (Exhibit E) at 121:18-122:7.

**20.** Watson maintained tiered product pricing for various classes of trade, which are the presumptive prices that would be charged to each particular customer. *See* Schein 30(b)(6) (Clark) 6/27/07 Dep. (Exhibit F) at 74:10-76:19; *see also* Recchia 10/11/07 Dep. (Exhibit B) at 40:18-44:4, 113:20-118:8; Exhibit R (Recchia 10/11/07 Dep. Exhibit 13 (Schein pricing grid listing AWP and WAC for various classes of trade including non-warehousing chains, warehousing chains, large and small nursing home providers and hospitals)); *see also* Recchia 10/11/07 Dep. (Exhibit B) at 143:15-145:14; Exhibit T (Recchia 10/11/07 Dep. Exhibit 19 (pricing grid listing by NDC the SWP, WAC and pricing levels for category levels B, D, D and E)); Schein 30(b)(6) (Clark) 6/27/07 Dep. (Exhibit F) at 71:9-75:19.

**21.** Because Mylan, contract sales which comprised the majority of its business, were always priced below WAC (*see* Deposition of Joseph Canny dated 12/2/05 ("Canny 12/2/05 Dep.") (Exhibit U) at 149:6-22, 151:7-11), Mylan knew that its published WACs were false. *Mylan*, 2008 WL 5650859 at \*26.

**Watson Marketed the Spread**

**22.** Watson knew that the reimbursement spread basically marketed itself, as it was self-evident to Watson's pharmacy customers for all of its drugs as they were aware of how they would be reimbursed by Medicaid. *See* Exhibit V (Barclay 11/21/05 Dep. Exhibit 13 (March 1996 pricing grid comparing the AWP's of Schein and Mylan)).

**23.** As opportunities to increase prices became limited, Watson lowered its AWP, knowing that it would affect an increase in the FUL resulting in increased reimbursement for Watson's drugs. *See* Recchia 10/11/07 Dep. (Exhibit B) at 146:11-152:2; Exhibit L (Recchia 10/11/07 Dep. Exhibit 21 (Schein memo, dated 8/27/96, approving a strategy intended to increase FUL)); *see also* Clark 12/1/05 Dep. (Exhibit H) at 107:8-108:21; Exhibit W (Clark 12/1/05 Dep. Exhibit 10 (Schein procedural document advising that a review of WAC should also include a comparison to FUL)); *see also* Schein 30(b)(6) (Clark) 6/27/07 Dep. (Exhibit F) at 54:12-56:16.

#### **Watson's Knowledge of the OIG Guidelines**

**24.** Watson knew about the OIG Guidelines. *See* Canny 12/02/05 Dep. (Exhibit U) at 75:7-17; Deposition of Timothy Callahan dated 11/29/05 (Exhibit X) at 546:6-15.

#### **Watson's AMPs**

**25.** Watson reports its average manufacturer's price ("AMP") to HHS. *See* Watson Answer at ¶ 62; *see also* Mylan, 2008 WL 5650859 at \*30.

Dated: May 15, 2009

Respectfully submitted,

**City of New York and New York Counties in  
MDL 1456 except Nassau and Orange by**

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**CERTIFICATE OF SERVICE**

I, James P. Carroll Jr., hereby certify that I caused a true and correct copy of the foregoing PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO WATSON PHARMACEUTICALS, INC. AND WATSON PHARMA, INC., to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties. The confidential exhibits to the foregoing have been served electronically directly to counsel for Watson Pharmaceuticals, Inc. and Watson Pharma, Inc.

Dated: May 15, 2009

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**CONFIDENTIAL EXHIBITS**

**TO  
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**MAY 15, 2009**

**SUBJECT TO MOTION FOR LEAVE TO FILE UNDER SEAL**